GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5870
ANSWERED ON:04.05.2005
PERMISSION FOR SHIPMENT OF A NEW DRUG
Bhadana Shri Avtar Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether specific permission for every shipment of a new drug has to be taken from the Drug Controller of India even though the same company has exported the same drug in the past;

(b) whether the Chemexcil has drawn the attention of the Government towards it and suggested that one time permission for specified period be given; and

(c) if so, the reaction of the Government thereto?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a), (b) & (c): As per present norms unapproved drugs which otherwise cannot be manufactured and marketed in the country are allowed to be manufactured for export on the basis of No Objection Certificate (NOC) issued by the office of Drugs Controller General (India). Such NOC`s are issued on the basis of export order. CHEMEXCIL has suggested for a general one-time permission for the manufacture of unapproved drugs for export. However, since, the approval granted by the State Licensing Authority for the manufacture of the said unapproved drugs is valid for the specific export order, the manufacturer is required to obtain NOC related to each specific export order.